FLORA.1100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Kleiman *et al.*	Atty Docket No.:	FLORA.1100
Serial No.:	09/899,432	Group Art Unit:	1617
Filed:	07/06/2001	Examiner:	Shobha Kantamneni

TITLE: **ANTIVIRAL COMPOSITION AND TREATMENT METHOD**

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class mail in an envelope addressed to " Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" on:

Date: _____ By: _____

Printed Name: _____

AFFIDAVIT
PURSUANT TO 37 C.F.R. §1.132

Assistant Commissioner of Patents
Alexandria, VA 22313-1450

Dear Assistant Commissioner:

STATE OF ARIZONA)
:
COUNTY OF MARICOPA)

I, David Ashley, being duly sworn, depose and say as follows:

I received a Bachelors of Science in Chemistry from Arizona State University in May of 1987. I have been employed by International Flora Technologies, Inc., (Technical Department) since 2003 where I serve as a chemist. Previously, I was employed at Safety-Kleen Systems, Inc., where I served as Compliance Manager from 2002-2003. I have also worked in various technical and managerial capacities at Onyx Environmental Services (Salesco Systems USA, Inc.), ADFlex Solutions Inc., and Revlon Consumer Products Corporation. I have over fourteen years of experience in analytical chemistry, environmental, health, and safety management. I am a Certified Hazardous Material Manager, and a member of the American Chemical Society.

I have undertaken an extensive review of United States Patent Application Serial No. 09/899,432. The invention referenced therein is directed to methods for treating virus-induced and inflammatory diseases utilizing compositions that include monounsaturated long chain alcohols in combination with long chain fatty acid salts and fatty acid esters. Specifically, the salts of fatty acids include salts of jojoba-derived fatty acid material.

It is known that the fatty acids of jojoba are made of essentially all cis-isomers. *See* excerpt from "Jojoba: New Crops for Arid Lands, New Raw Material for Industry", Report of an Ad Hoc Panel of the Advisory Committee on Technology Innovation Board on Science and Technology for International Development Office of International Affairs National Research Council (1985), *attached as* Exhibit 1. This is evidenced by, for example, the fact that no trans-isomers are present prior to isomerization of jojoba oil. *See* Jaime Wisniak, THE CHEMISTRY AND TECHNOLOGY OF JOJOBA OIL, p. 87 (1987), *attached as* Exhibit 2. In other words, jojoba oil that has not undergone the process of isomerization is considered "trans-free".

Additionally, when fatty alcohols and fatty acids derived from jojoba oil are analyzed using infrared spectrophotometry, an absence of absorption at 10.36 microns indicates that all ethylenic bonds [of fatty alcohols and fatty acids derived from jojoba oil] are *cis* in geometric configuration. *See* Wisniak, at p. 43, *attached as* Exhibit 3. Therefore, fatty acids and fatty alcohols derived from jojoba oil are considered "trans-free".

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States

Code and that such willful and false statements may jeopardize the validity of the subject patent application or any patent issued thereon.

I further declare that I have received no special compensation or consideration for making this affidavit, nor have I been in any way told, either directly or by implication or inference, by anyone that my employment by International Flora Technologies, Inc., or my professional advancement or other matters of personal or professional interest to me depend in any way on whether or not I make this affidavit or the content thereof. I further declare that I make this affidavit of my own free will and choice without any duress or influence of any kind, believing fully in the truth of the statements made by myself herein.

David Ashley

I, Carol Hynes, a Notary Public in and for the County and State aforesaid, do hereby certify that David Ashley, whose name is subscribed to the foregoing instrument, appeared before me this day in person and acknowledge that he signed, sealed and delivered the said instrument as his free and voluntary act and deed for the uses and purposes therein set forth.

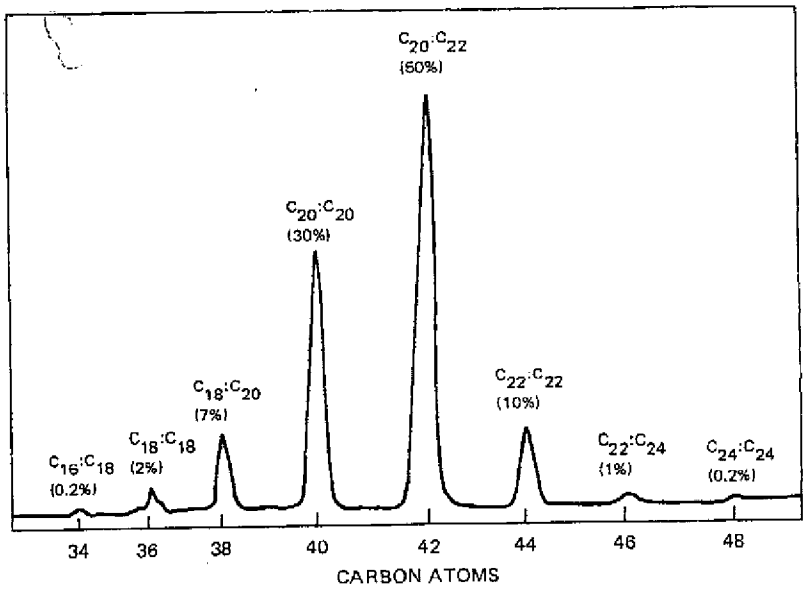
Given under my hand and Notary Seal this 7th day of Nov. 2007.

My commission expires on Nov. 29, 2007

SEAL

OFFICIAL SEAL
CAROL HYNES
NOTARY PUBLIC - State of Arizona
MARICOPA COUNTY
My Comm. Expires Nov. 29, 2007

EXHIBIT 1



Jojoba oil esters are made up of fatty alcohols and fatty acids that are predominantly 20 or 22 carbon atoms long. Compared with most vegetable oils, the carbon chain lengths are remarkably uniform. (Information from T.K. Miwa)

alcohols are a mixture of eicosanol and docosanol, with smaller quantities of hexacosanol and alcohols of lower molecular weight.

The acids and alcohols that make up jojoba oil each have a single double bond. Moreover, all double bonds are in the ω_9 position (i.e., between carbon 9 and carbon 10, counting from the methyl end). This is a remarkable molecular purity, and the double bond position is different from that usually found in vegetable oils.

The nature of the oil can be grossly changed by reactions at the double bonds and ester functions, and many new products can result. One research laboratory in Israel, for example, has produced more than 40 different jojoba-based chemicals that appear to have commercial industrial applications.*

As in other natural oils, the double bonds in fresh jojoba oil are all in the *cis* configuration. However, they can be easily isomerized (twisted around in space), using as catalysts traces of selenium, nitrogen oxides, or active earth. This produces an equilibrium mixture with 20 percent *cis* and 80 percent *trans* double bonds. This simple process dramatically transforms the liquid into a soft, opaque cream resembling face cream. It can be stopped at various intermediate degrees of

* Information from A. Shani and J. Wisniak.

JOJOBA

New Crop for Arid Lands, New Raw Material for Industry

Report of an Ad Hoc Panel of the
Advisory Committee on Technology Innovation
Board on Science and Technology
for International Development
Office of International Affairs
National Research Council

NATIONAL ACADEMY PRESS
Washington, D.C. 1985

EXHIBIT 2

THE CHEMISTRY AND TECHNOLOGY OF

JOJOBA OIL

JAIME WISNIAK

American Oil Chemists' Society
Champaign, Illinois

percent nitrous acid. A 70% yield of *trans* isomer was obtained with no migration of the double bond. Their results indicated that the isomerization is induced initially by the nitrogen dioxide anion and followed immediately by complex formation between the excited triplet anion and the olefin. Crystallization of the final product yielded a solid that contained 96–97% of the *trans* form (brassidic acid) and melted at 58–59 C. The *cis* and *trans* double bonds in erucic and brassidic acids were identified by NMR, and absence of double bond migration was verified by reductive microozonolysis-GLC analysis. Chang and Miwa also explained the known fact that erucic acid has a high thermal stability against geometrical isomerization, on the basis of the reluctance of the excited singlet states to cross over to the triplet states. The extremely short-lived excited singlets need sensitization by stable triplets or by readily excitable free radicals like NO_2^- and NO_2.

Wisniak (17) and Wisniak and Alfandary (18) were the first to report on the geometrical isomerization of jojoba oil with selenium and NO_2 catalysts under a wide range of conditions. Isomerization runs with selenium were conducted in a resin flask provided with heating and agitation. Overall time of reaction varied between 45 and 150 min, with 0.094–0.4% selenium, and temperatures 180–210 C.

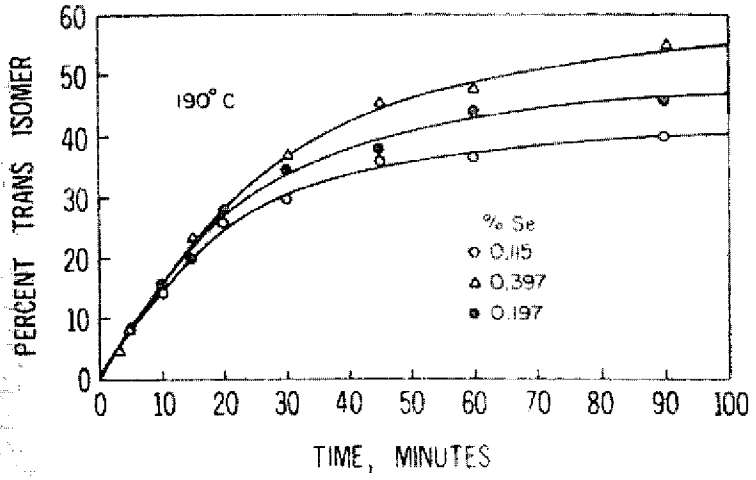


Fig. 2-4. Isomerization at 190 C with selenium (18)

EXHIBIT 3

ester, 10%; and for the fatty acids and alcohols—octadecenoic acid, 6%; eicosenoic acid, 35%; docosenoic acid, 7%; eicosenoi, 22%; docosenol, 21%; and tetracosenol, 4%. On the basis of these results, Miwa (53) concluded that the liquid esters were not biosynthetized by random esterification of the fatty acids and alcohols. The GLC technique developed by Miwa has been improved by Duncan et al. (81) to decrease the time required by the HCl-hydrolysis step. They found that the wax is hydrolyzed faster by refluxing it in 5% HCl in anhydrous ethanol.

A more refined analysis using GLC coupled with high-pressure liquid chromatography, mass spectrometry and ozonolysis was

TABLE 1-26

Composition and Structure of Fatty Alcohols and Fatty Acids Derived from Jojoba Oil (Analysis by GLC, Ozonolysis-GC and GC-MS[a]

Alcohols	(%)	Acids	(%)
Tetradecanol	trace[b]	Dodecanoic	trace
Hexadecanol	0.1	Tetradecanoic	trace
Heptadec-8-enol	trace	Pentadecanoic	trace
Octadecanol	0.2	Hexadecanoic	1.2
Octadec-9-enol	0.7	Hexadec-7-enoic	0.1
Octadec-11-enol	0.4	Hexadec-9-enoic	0.2
Eicosanol	trace	Heptadecenoic	trace
Eicos-11-enol	43.8	Octadecanoic	0.1
Hecos-12-enol	trace	Octadec-9-enoic	10.1
Docosanol	1.0	Octadec-11-enoic	1.1
Docos-13-enol	44.9	Octadecadienoic	0.1
Tetracos-15-enol	8.9	Octadecatrienoic	trace
Hexacosenol	trace	Nonadecenoic	trace
		Eicosanoic	0.1
		Eicos-11-enoic	71.3
		Eicosadienoic	trace
		Docosanoic	0.2
		Docos-13-enoic	13.6
		Tricosenoic	trace
		Tetracosenoic	trace
		Tetracos-15-enoic	1.3

[a]Miwa (83, 84).

[b]Trace denotes 0.01–0.05%. Absence of absorption at 10.36 microns in infrared spectrophotometry indicates all ethylenic bonds to be *cis* in geometric configuration.

Mention of firm names or trade products does not imply endorsement or recommendation by the editors or contributors over other firms or similar products not mentioned.

Library of Congress Cataloging-in-Publication Data

Wisniak, Jaime.
The chemistry and technology of jojoba oil.

Bibliography: p.
Includes index.
1. Jojoba products. I. Title.
TP684.J64W57 1987 665'.35 87-22962
ISBN 0-935315-17-9

Printed in the United States of America